510(k) Summary of Safety and Effectiveness

Submitted by:
Pharos Life Corporation
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Cambridge, Ontario
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JAN - 3 2011

The assigned 510(k) number is: K103415

1. **Date Prepared:**
   Dec 8 2010

2. **Contact Person:**
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3. **Device Name and Classification:**

Device Name	Tanda Max
Classification Name	Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Common Name	LED Light System
Device Classification	2
Review Panel	General and Plastic Surgery
Product Code	GEX
Regulation Number	878.4810

4. **Predicate Devices:**

Predicate Device Name(s)	Applicant	510(k) Number	Product Code
Lumiphase-R	Opusmed	K051255	GEX

K163415

5. **Device Description**
Tända Max is a modular system that offers simplicity in use and convenience. The system can operate while connected directly to an electrical outlet or can be used in cordless mode drawing upon its rechargeable batteries to deliver the treatment. The system components include the control unit, the treatment head, recharging stand, Pre-treatment gel, AC adapter and goggles.

Tanda Max utilizes red light at 660 nm. The unit is applied directly to the skin to ensure consistent administration of light during each treatment. The surface that comes into contact with the skin has been selected to ensure the light is administered to the skin while providing a smooth surface for cleaning.

6. **Intended Use:**
The Tända Max System is intended for the treatment of wrinkles, rhytides and fine lines in the periorbital region.

7. **Comparison of Technological Differences**
The technological characteristics of Tanda Max are equivalent to the listed predicate devices. Specifically, Tanda Max:
   1. Has the same intended use as the predicate (i.e., Treatment of wrinkles, rhytides and fine lines;
   2. Has the same output (i.e., 50 mW/cm^2) as the predicate;
   3. Utilizes the same wavelength (i.e., 660 nm) as the predicate device;
   4. Utilizes the same treatment duration (i.e., 160 seconds) as the predicate device;
   5. Utilizes the same treatment regimen (i.e., two treatments per week for six weeks) as the predicate device.

Any differences between the Tanda Max System and the predicate device are not significant to its safety or effectiveness for its intended use.

8. **Summary of non-clinical testing**
Tanda Max meets the requirements of IEC 60601-1(electrical safety), IEC 60601-1-2 (EMC and EMI), IEC 60825 (Laser Safety), and ISO 10993 (biocompatibility).

9. **Clinical Information**
Based on the above information, additional clinical information is not necessary.

10. **Conclusion**
Tanda Max meets the safety and efficacy requirements necessary for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pharos Life Corporation
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

JAN - 3 2011

Re: K103415
Trade/Device Name: Tända Max System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONE
Dated: December 21, 2010
Received: December 22, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K103415

Device Name: **Tända Max System**

Indications For Use:

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The Tända Max System is intended for the treatment of wrinkles, rhytides and fine lines in the periorbital region.

Prescription Use X AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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